

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

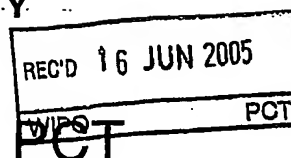
Applicant's or agent's file reference DC5078 PCT 1	FOR FURTHER ACTION	See item 4 below
International application No. PCT/US2005/004758	International filing date (<i>day/month/year</i>) 10 February 2005 (10.02.2005)	Priority date (<i>day/month/year</i>) 12 March 2004 (12.03.2004)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant DOW CORNING CORPORATION		

1.	This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).																								
2.	This REPORT consists of a total of 8 sheets, including this cover sheet. In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.																								
3.	<p>This report contains indications relating to the following items:</p> <table style="width: 100%;"> <tr> <td style="width: 10%; text-align: center;"><input checked="" type="checkbox"/></td> <td style="width: 40%;">Box No. I</td> <td style="width: 50%;">Basis of the report</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>	<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input checked="" type="checkbox"/>	Box No. VII	Certain defects in the international application	<input checked="" type="checkbox"/>	Box No. VIII	Certain observations on the international application
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4.	The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).																								

<p style="text-align: center;">The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland</p> <p>Facsimile No. +41 22 338 82 70</p>	<p>Date of issuance of this report 13 September 2006 (13.09.2006)</p> <p>Authorized officer Dorothee Mülhausen</p> <p>e-mail: pt01@wipo.int</p>
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PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY



To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION See paragraph 2 below

International application No.
PCT/US2005/004758

International filing date (day/month/year)
10.02.2005

Priority date (day/month/year)
12.03.2004

International Patent Classification (IPC) or both national classification and IPC
A61K9/70, A61K47/34, A61K31/00, C08L83/04, A61L15/58, A61K47/10

Applicant
DOW CORNING CORPORATION

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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Authorized Officer

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2005/004758

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2005/004758

Box No. V Reasoned statement under Rule 43b/s.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	1-18
Inventive step (IS)	Yes: Claims	
	No: Claims	1-18
Industrial applicability (IA)	Yes: Claims	1-18
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item I.

- 1) Although claims 1 and 12, directed to a method claim, have been drafted as separate independent claims. They appear to relate effectively to the same subject-matter, namely a method of making, and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness. Moreover, lack of clarity of the claims as a whole arises, since the plurality of independent claims makes it difficult, if not impossible, to determine the matter for which protection is sought, and **places an undue burden** on others seeking to establish the extent of the protection.

Hence, claims 1 and 23 do not meet the requirements of Article 6 PCT.

This applies to independent claims 17 and 18 which are both directed to a product claim.

In order to overcome this objection, it would appear appropriate to file an amended set of claims defining the relevant subject-matter in terms of a single claim in each category followed by dependent claims covering features which are merely optional (Rule 6.4 PCT). Applicant should take care however not to add subject-matter which extends beyond the content of the application (Art. 19/34 PCT).

Failure to do so or to give convincing argumentations might lead to the substantive examination of only the first independent claim and its appending claims.

Re Item V.

- 2) The documents cited in the International Search Report (ISR) were numbered respectively from D1-D8; this numbering results from the citation order in the ISR and will be used for the procedure. **Unless otherwise specified, the cited passages of each document in the ISR will be considered.**

D1 : US 5 035 894 A (LEE ET AL) 30 July 1991 (1991-07-30)

D2 : US 5 658 975 A (ULMAN ET AL) 19 August 1997 (1997-08-19)

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/US2005/004758

D3 : US 4 840 796 A (SWEET ET AL) 20 June 1989 (1989-06-20)
D4 : US 5 556 636 A (YANO ET AL) 17 September 1996 (1996-09-17)
D5 : US 5 114 707 A (CYPRIEN ET AL) 19 May 1992 (1992-05-19)
D6 : US 2003/180281 A1 (BOTT RICHARD R ET AL) 25 September 2003 (2003-09-25)
D7 : US 4 814 184 A (AGUADISCH ET AL) 21 March 1989 (1989-03-21)
D8: DOW CORNING: "Product Information: Dow Corning 9011"[Online] 26 April 2002 (2002-04-26), XP002330255 Retrieved from the Internet:
URL:http://www.dowcorning.com/DataFiles/09_0007b580108c93.pdf [retrieved on 2005-06-01]

3) Novelty and inventive step according to Art. 33(2) and 33(3) PCT

- 3a) The subject-matter of present application is not novel and/or not inventive because D1-D7 (see relevant passage in the ISR) seem to describe an adhesive matrix, and a method of manufacturing it, said matrix contains a hydrophilic substance (a drug or an excipient), a silicone polyether dispersed in a silicone pressure sensitive adhesive.
- 3b) It could be argued that the D1-D7 do not provide exactly and in a convincing manner that the hydrophilic substance is in **solid powdered form**. Nevertheless, the **use of the same silicone polyether and hydrophobic silicone pressure sensitive adhesive would inherently and implicitly leads to the same effects** as described in present application, namely a matrix of a hydrophobic silicone wherein solid particles of a hydrophilic substances are dispersed using a polyether silicone. In such a case an objection as to lack of novelty arises in the first place and **the burden is on the Applicant to provide evidence** for the novelty of the claimed composition and method.

Such evidence should be of a technical character (for instance experimental data or conclusive arguments; see also guidelines **C-IV, 7.5.**). In particular the applicant should demonstrate that

- the composition of prior art is not a dispersion of solid particles
- if so, that the emulsified droplets do not solidify after a while.

Furthermore he should also show that the hydrophilic particles dispersed in the hydrophobic matrix are really in a solid state using a polyether silicone.

- 3c) Should the applicant renders the subject-matter of independent claims novel by pointing out the importance of a feature, or by introducing into the claims the use of a **specific excipient or a specific range or a specific process** or whatever, inventive step may be recognized **only if he demonstrates** that the introduced technical feature provides a **surprising or synergetic effect** that the skilled man in the art will not be able to deduct from the prior art.
In the absence of a surprising effect, inventive step cannot be acknowledged because the introduced technical feature will be considered as an **obvious alternative** that the skilled man in the art will perform **routinely** in order not to interact with prior art.
- 3d) If the applicant is able to show, e.g. by **appropriate comparison tests**, that differences do exist with respect to the physical form of the dispersed particles, it is questionable whether the independent claims disclose **all the features essential to manufacture products having parameters specified in the claims** (Art. 5 and 6 PCT).
- 3e) Any information the applicant may wish to submit concerning the subject-matter of the invention, for example further details of its advantages or of the problem it solves, and for which there is no basis in the application as filed, should be confined to the letter of reply and not be incorporated into the application.

Re Item VII.

- 4) Contrary to the requirements of Rule 5.1(a)(ii) PCT, it seems that the relevant background art disclosed in the documents D1-D7 is not mentioned in the description, nor are these documents identified therein.
- 5) The attention of the applicant is drawn to the fact that the application may not be amended in such a way that it contains subject-matter **which extends beyond the content of the application as filed**.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/US2005/004758

In order to facilitate the examination of the conformity of the amended application with the requirements of Article 34(2)(b) PCT, the applicant is requested to clearly identify the amendments carried out, no matter whether they concern amendments by addition, replacement or deletion, and to indicate the passages of the application as filed on which these amendments are based (see also Rule 66.8(a) PCT).

Preferably these indications should be submitted in handwritten form on a copy of the relevant parts of the application as filed.

- 6) The applicant is kindly requested to take account of the above objections and **give convincing argumentations**. Should the applicant regard some particular matter as patentable, an independent claim should be filed taking account of Rule 6.3(b) (I), (ii) PCT (two part form claim). The applicant should also indicate in the letter of reply **the difference of the subject-matter of the new claim vis-à-vis the state of the art and the significance thereof**.

Re Item VIII.

- 7) Too many independent claims: see herein §1 (Art.6 PCT)